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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,904	09/07/2004	Yehoshua Yeshurun	1975/43	7073

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Mark M Friedman
Bill Polkinghorn
9003 Florin Way
Upper Marlboro, MD 20772

EXAMINER

SMITH, PAUL B

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,904	YESHURUN ET AL.	
	Examiner	Art Unit	
	Paul B. Smith	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/IL03/00165, filed on 3/4/2003.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/29/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the references cited therein are considered by the examiner.

Claim Objections

3. Claims 1, 2, 11, 13, 14, 24, 26, 32 and 46 objected to because of the following informalities: The terms "said surface", "said planar surface" and "said substantially planar surface" are used inconsistently throughout the aforementioned claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 7-8, 10-11, 13, 19-20, 22-24, 26-29, 32-35, and 49-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmer ('242).

6. Palmer discloses a device for penetration of a member for the intradermal sampling or administration of a substance consisting of a planar surface (22), a plurality of microneedles (43), and an abutment member (48). The path of movement of the microneedles has a non-zero component parallel to the planar surface relative to the abutment member. Each microneedle is formed with a conduit (40) extending from the penetrating tip through the bottom wall (22) to the cavity (24). (See Figure 3)

7. The path of movement for the device carries the planar surface (22) from an initial position above the abutment member (48) to a deployed position below the abutment member (48). (See Figure 5)

8. The abutment member (48) encircles the fluid transport configuration (12) initially and deployed. (See Figure 4)

9. Palmer teaches that an adhesive can be applied to abutment member (48) to grip the barrier membrane. (See Column 8, Lines 12-15)

10. Palmer discloses dimensions of the microneedle. The microneedle length is about 200 microns to about 1500 microns. The microneedle width can be about 15 to 40 gauge. (See Column 7, Lines 5-19)

11. Claim 38-39 rejected under 35 U.S.C. 102(b) as being anticipated by Roser ('896).

12. Roser teaches a method for injecting fluid through a biological barrier comprising a hollow needle and a high velocity flow of fluid. The high velocity fluid flow is generated exclusively by force applied manually to the flow actuation mechanism (10). (See Example 5, Column 13, Line 45)

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 2-6, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer ('242) in view of Tobinaga ('463).

16. Palmer discloses a device for penetration of a member for the intradermal sampling or administration of a substance consisting of a planar surface (22), a plurality of microneedles (43), and an abutment member (48). The path of movement of the microneedles has a non-zero component parallel to the planar surface relative to the abutment member. Each microneedle is formed with a conduit (40) extending from the penetrating tip through the bottom wall (22) to the cavity (24). (See Figure 3)

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17. The path of movement for the device carries the planar surface (22) from an initial position above the abutment member (48) to a deployed position below the abutment member (48). (See Figure 5)

18. The abutment member (48) encircles the fluid transport configuration (12) initially and deployed. (See Figure 4)

19. Palmer teaches that an adhesive can be applied to abutment member (48) to grip the barrier membrane. (See Column 8, Lines 12-15)

20. Palmer fails to disclose specific microneedle configurations.

21. Tobinaga teaches microneedles being asymmetrical such that a base-to-tip vector is non-perpendicular to the planar surface. (See Figure 14a-c)

22. Tobinaga further teaches that the projection of the penetrating tip onto the planar surface lies within the base area of the microneedle. (See Figure 1)

23. Tobinaga discloses microneedles formed with at least one sidewall standing substantially perpendicular to the planar surface and at least one wall inclined relative to a perpendicular to the planar surface. (See Figure 8)

24. Tobinaga further discloses microneedles formed with at least two sidewalls each having a substantially planar face and being positioned such that an angle between the faces is between 30° and 70°. (See Figure 14a and 14c)

25. It would have been obvious to one of ordinary skill in this art at the time the invention was made to have incorporated the teachings of Tobinaga with those of Palmer to provide microneedles that were capable of penetration for a transdermal delivery of fluid.

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26. Claims 9, 21, 30, 36, 40, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer ('242) in view of Peterson ('163).

27. Palmer discloses a device for penetration of a member for the intradermal sampling or administration of a substance consisting of a planar surface (22), a plurality of microneedles (43), and an abutment member (48). The path of movement of the microneedles has a non-zero component parallel to the planar surface relative to the abutment member. Each microneedle is formed with a conduit (40) extending from the penetrating tip through the bottom wall (22) to the cavity (24). (See Figure 3)

28. The path of movement for the device carries the planar surface (22) from an initial position above the abutment member (48) to a deployed position below the abutment member (48). (See Figure 5)

29. The abutment member (48) encircles the fluid transport configuration (12) initially and deployed. (See Figure 4)

30. Palmer teaches that an adhesive can be applied to abutment member (48) to grip the barrier membrane. (See Column 8, Lines 12-15)

31. Palmer fails to disclose a flow actuation mechanism that generates a driving pressure of at least 1,000 PSI to produce a high velocity fluid jet emerging from the conduits.

32. Petersen discloses a device that generates a driving pressure of about 1,200 PSI to 1,800 PSI to deliver the medicate by a high velocity fluid jet generated by force applied manually to the flow actuation mechanism. (Column 19, Line 50)

33. It would have been obvious to one of ordinary skill in this art at the time of the invention was made to have incorporated the teachings of Peterson with those of Palmer to provide a device for transporting fluid across a biological barrier with a high velocity fluid jet.

34. Claims 12, 25, 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer ('242) in view of Eppstein ('611) and in further view of Paul ('783).

35. Palmer discloses a device for penetration of a member for the intradermal sampling or administration of a substance consisting of a planar surface (22), a plurality of microneedles (43), and an abutment member (48). The path of movement of the microneedles has a non-zero component parallel to the planar surface relative to the abutment member. Each microneedle is formed with a conduit (40) extending from the penetrating tip through the bottom wall (22) to the cavity (24). (See Figure 3)

36. The path of movement for the device carries the planar surface (22) from an initial position above the abutment member (48) to a deployed position below the abutment member (48). (See Figure 5)

37. The abutment member (48) encircles the fluid transport configuration (12) initially and deployed. (See Figure 4)

38. Palmer teaches that an adhesive can be applied to abutment member (48) to grip the barrier membrane. (See Column 8, Lines 12-15)

39. Palmer fails to disclose a vibration generator to enhance the penetration of the microneedles.

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40. Eppstein teaches enhancement of transdermal delivery with ultrasound. (See Abstract)

41. Paul discloses a drive structure for reciprocating a tattoo needle. (See Abstract)

42. It would have been obvious to one of ordinary skill in this art at the time the invention was made to have used the disclosure of Palmer with the teachings of Eppstein in conjunction with the device disclosed by Paul to provide a vibration generator capable of enhancing penetration of microneedles into the biological barrier.

43. Claims 41-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roser ('896).

44. It would have been obvious to one of ordinary skill in the art to modify the depth as claimed as a mere design choice lacking any criticality of depth as being merely preferable for the intended target (intradermal) area depending on the thickness of the skin of the patient where the only difference between the prior art and the claims was a recitation of relative delivery depths of the claimed device and a device having the claimed relative depths would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art

Conclusion

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

46. The following patents are cited to further show the state of the art with respect to devices and methods for transporting fluid across a biological barrier in general:


47. U.S. Pat. No. 5,399,163 to Peterson

- 48. U.S. Pat. No. 6,537,242 to Palmer
- 49. U.S. Pat No. 4,031,783 to Paul
- 50. U.S. Pat No. 5,445,611 to Eppstein
- 51. U.S. Pub. No. 2005/0065463 to Tobinaga

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is (571) 272-6022. The examiner can normally be reached on 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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